



Mar 3 2006  
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**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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IN RE PHARMACEUTICAL INDUSTRY )  
AVERAGE WHOLESALE PRICE ) MDL NO. 1456  
LITIGATION ) Civil Action No. 01-12257-PBS

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THIS DOCUMENT RELATES TO: ) Judge Patti B. Saris

*The City of New York v. Abbott Labs., et al.* )  
(S.D.N.Y. No. 04-CV-06054) )  
*County of Suffolk v. Abbott Labs., et al.* )  
(E.D.N.Y. No. CV-03-229) )  
*County of Westchester v. Abbott Labs., et al.* )  
(S.D.N.Y. No. 03-CV-6178) )  
*County of Rockland v. Abbott Labs., et al.* )  
(S.D.N.Y. No. 03-CV-7055) )  
*County of Dutchess v. Abbott Labs, et al.* )  
(S.D.N.Y. No. 05-CV-06458) )  
*County of Putnam v. Abbott Labs, et al.* )  
(S.D.N.Y. No. 05-CV-04740) )  
*County of Washington v. Abbott Labs, et al.* )

[Caption Continues on Next Page]

**BIAGEN IDEC INC.'S SEPARATE MEMORANDUM OF LAW IN SUPPORT OF ITS  
MOTION TO DISMISS (1) THE CONSOLIDATED COMPLAINT OF NEW YORK  
CITY AND PLAINTIFF NEW YORK COUNTIES OTHER THAN NASSAU AND  
(2) THE SECOND AMENDED COMPLAINT OF NASSAU COUNTY**

(N.D.N.Y. No. 05-CV-00408) )  
*County of Rensselaer v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00422) )  
*County of Albany v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00425) )  
*County of Warren v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00468) )  
*County of Greene v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00474) )  
*County of Saratoga v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00478) )  
*County of Columbia v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00867) )  
*County of Essex v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00878) )  
*County of Chenango v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00354) )  
*County of Broome v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00456) )  
*County of Onondaga v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00088) )  
*County of Tompkins v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00397) )  
*County of Cayuga v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00423) )  
*County of Madison v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00714) )  
*County of Cortland v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00881) )  
*County of Herkimer v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00415) )  
*County of Oneida v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00489) )  
*County of Fulton v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00519) )  
*County of St. Lawrence v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00479) )  
*County of Jefferson v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00715) )  
*County of Lewis v. Abbott Labs, et al.* )  
 (N.D.N.Y. No. 05-CV-00839) )  
*County of Chautauqua v. Abbott Labs, et al.* )  
 (W.D.N.Y. No. 05-CV-06204) )  
*County of Allegany v. Abbott Labs, et al.* )  
 (W.D.N.Y. No. 05-CV-06231) )  
*County of Cattaraugus v. Abbott Labs, et al.* )  
 (W.D.N.Y. No. 05-CV-06242) )  
*County of Genesee v. Abbott Labs, et al.* )  
 (W.D.N.Y. No. 05-CV-06206) )  
*County of Wayne v. Abbott Labs, et al.* )  
 (W.D.N.Y. No. 05-CV-06138) )

<i>County of Monroe v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06148)	)
<i>County of Yates v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06172)	)
<i>County of Niagara v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06296)	)
<i>County of Seneca v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06370)	)
<i>County of Orleans v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06371)	)
<i>County of Ontario v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06373)	)
<i>County of Schuyler v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06387)	)
<i>County of Steuben v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06223)	)
<i>County of Chemung v. Abbott Labs, et al.</i>	)
(W.D.N.Y. No. 05-CV-06744)	)
AND	)
<i>County of Nassau v. Abbott Labs, et al.</i>	)
(E.D.N.Y. No. 04-CV-5126)	)
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Defendant Biogen Idec Inc. (“Biogen”) respectfully submits this Memorandum of Law in further support of its motion to dismiss the consolidated complaint of New York City and plaintiff New York Counties other than Nassau County (“Consolidated Complaint” or “Cons. Compl.”) and the Second Amended Complaint of Nassau County (“Nassau SAC”).<sup>1</sup> Biogen is one of the “Suffolk 13+6” defendants against whom the Court has dismissed all claims asserted by Suffolk County.<sup>2</sup> For the reasons detailed below, the deficiencies that resulted in dismissal of those claims against Biogen in *Suffolk* remain in the Consolidated Complaint and Nassau SAC.

### **I. PLAINTIFFS ALLEGE CLAIMS ONLY AS TO ONE PRODUCT, AVONEX®**

In January 2003, this Court advised class action plaintiffs that in order to survive a motion to dismiss they must “particularize exactly what drugs, exactly what the fraud is, [and] which plaintiffs paid for what drugs.” *See* Tr. Of Jan. 13, 2003 Hearing on Motion to Dismiss, at 74. In May 2003, this Court reaffirmed its statements, instructing the plaintiffs that they must “clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant; (2) the allegedly fraudulent AWP for each drug; and (3) the name of the specific plaintiff(s) that purchased the drug.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003).

Although both complaints refer to Biogen’s Amevive® and Zevalin®<sup>3</sup> drugs (Cons. Compl. ¶¶ 332-334, Nassau SAC ¶¶ 312-315), none of the plaintiffs allege purchases of either

<sup>1</sup> Biogen hereby adopts and incorporates herein each of the arguments set forth in the Defendants’ Joint Memorandum of Law in Support of Motion to Dismiss (1) the Consolidated Complaint of New York City and Plaintiff New York Counties Other Than Nassau and (2) The Second Amended Complaint of Nassau County (“Defendants’ Joint Memorandum”). Biogen also joins in and incorporates by reference the arguments made in the briefs filed by the other defendants to the extent they apply to Biogen.

<sup>2</sup> *County of Suffolk v. Abbott Labs, et al.*, 339 F. Supp. 2d 165 (D. Mass. Sept. 30, 2004); *County of Suffolk v. Abbott Labs, et al.*, 2004 WL 2387125 (D. Mass. Oct. 26, 2004); Memorandum and Order dated April 8, 2005.

<sup>3</sup> Both complaints refer in passing to a Biogen drug named “Zeralin.” (Cons. Compl. ¶ 331, Nassau SAC ¶ 312.) Biogen does not manufacture or sell a drug named “Zeralin.” Biogen suggests that plaintiffs may have intended to refer to its drug Zevalin®.

Amevive® or Zevalin®, and none of the plaintiffs allege “fraudulent AWP” for either drug.<sup>4</sup> The plaintiffs therefore lack standing to assert claims based on these drugs. *See In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d at 193 (to satisfy constitutional requirements for Article III standing, plaintiff must allege “personal injury fairly traceable to the defendant’s allegedly unlawful conduct.”) (*quoting Allen v. Wright*, 468 U.S. 737, 751 (1984); *id.* at 177 (“The Court also dismisses ... all claims regarding drugs that are not identified by name with a specified fraudulent AWP...”). The only Biogen drug that plaintiffs allege they purchased is Avonex®.

## **II. THE ALLEGATIONS REGARDING AVONEX® LACK THE SPECIFICITY REQUIRED BY RULE 9(B)**

Federal Rule of Civil Procedure 9(b) provides that “in all averments of fraud ... the circumstances constituting fraud ... shall be stated with particularity.” Simply put, Rule 9(b) requires that a plaintiff plead the “who, what, where, and how” of the alleged fraud. *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001).

### **A. Plaintiffs Fail To Allege AWP Allegations With Particularity**

The plaintiffs fail to allege any particularized facts about Avonex®’s AWP, much less any facts which, if proven, would constitute fraud. The Consolidated Complaint provides only one specific allegation regarding Avonex®’s AWP: the so-called “Fraudulent AWP” listed in Exhibit A. Unlike for other defendants, the Consolidated Complaint fails to allege a “market price,” “spread,” or “price date” for any Biogen drugs, as Avonex® is not even listed in Exhibit

<sup>4</sup> The Consolidated Complaint explicitly states, “As set forth in detail in Exhibit A, the Counties’ Medicaid programs spent over \$31.5 million for Biogen Idec drugs between 1997-2003 alone. The specific drugs for which the Counties seek relief include those set forth in Exhibit A hereto.” Cons. Compl. ¶ 328. *See also* Cons. Compl. ¶ 1 (“The specific prescription drugs at issue (hereinafter the “subject drugs”) are attached as Exhibit A...”). Exhibit A to the Consolidated Complaint only alleges purchases of Avonex® Admin Pack 30 MCG VL. Similarly, Nassau alleges that it “spent approximately \$489,285 for Biogen Idec drugs between 1997-2003, as presented in Exhibit B, which also lists the specific drugs for which Nassau County seeks relief....” Nassau SAC ¶ 307. Exhibit B to the Nassau SAC only alleges purchases of Avonex® Admin Pack 30 MCG VL.

B.<sup>5</sup> As Defendants' Joint Memorandum notes, the Consolidated Complaint fails to adequately describe how it determined the "Fraudulent AWP" or, more importantly, identify any facts on which it based this price. *See* Defendants' Joint Memorandum at 27-28. Merely labeling an AWP "fraudulent" is insufficient to plead fraud under Rule 9(b), especially in the absence of any allegations regarding an alleged "market price" or "spread". Accordingly, the AWP-based claims in the Consolidated Complaint must be dismissed.

The Nassau SAC is even more deficient, as Nassau does not even allege *any* particular facts about Avonex®. Although the complaint, in paragraphs 308-309, alleges, "Exhibit A shows examples of the generally available market prices for the Biogen drugs at issue....Biogen Idec's marketing scheme is evidenced by Exhibit A," *Exhibit A does not list any Biogen drugs*. The complaint and exhibits fail to contain *any* particular allegations about Avonex®'s alleged "fraudulent AWP," "price date," "market price" or "spread." Accordingly, the Nassau SAC fails to satisfy Rule 9(b) and all AWP-based claims in the complaint must be dismissed.<sup>6</sup>

B. Plaintiffs' Best Prices Allegations Against Biogen Are Still Woefully Deficient Under Rule 9(b)

As discussed *supra*, plaintiffs do not allege purchases of either Amevive® or Zevalin® and do not have standing to allege best prices violations involving these drugs. The only Biogen drug any of the plaintiffs allege they purchased is Avonex®.

The sum total of plaintiffs' "best prices" allegations relating to Avonex® is contained in one paragraph of the 914-paragraph Consolidated Complaint and an identical paragraph in the 814-paragraph Nassau SAC. (Cons. Compl. ¶ 335, Nassau SAC ¶ 316). This paragraph, copied

<sup>5</sup> Exhibit B contains the alleged "Price Date," "Fraudulent AWP," "Market Price" and percentage "Spread" for the drugs at issue.

<sup>6</sup> *See also County of Suffolk*, 2004 WL 2387125 at \*2 (dismissing AWP claims against certain defendants "because there are no factual allegations regarding a spread, internal documents or government investigations from which an inference of fraud can reasonably be made.").

from an unverified complaint pending in an unrelated employment discrimination suit, fails to support the plaintiffs' allegations of "best prices" fraud. Plaintiffs do not identify a single allegedly fraudulently reported "best price" for Avonex®, let alone who submitted such a false report or the date of any such false report.<sup>7</sup> Simply baldly asserting, on information and belief, that alleged "defacto discounts" were not accounted for in Biogen's "best price" calculation does not satisfy Rule 9(b). *See U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 (1<sup>st</sup> Cir. 2004) (plaintiff must plead the "time, place, and content of the alleged false or fraudulent representations"); *U.S. ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (Saris, J.) (dismissing *qui tam* complaint alleging that vendors submitted invoices to hospitals that did not reflect discounts and credits – causing the hospitals to submit false claims for Medicare reimbursement – where complaint did not "identify or describe any specific ... reports or transactions." The complaint merely "sets out a methodology by which the [defendants] might have produced false invoices, which in turn could have led to false claims. Without citing a single false claim arising from an allegedly false invoice, [Plaintiff] has not met even a bare-bones Rule 9(b) test."). *See also Ex rel. G. Michael Gublo, et al. v. Novacare, Inc.*, 62 F. Supp. 2d 347, 354 (D. Mass. 1999) (dismissing claim under Rule 9(b) where plaintiff alleged three methods by which defendant allegedly inflated its bills to the government, but failed to cite a single instance of a false claim).

### **III. CONCLUSION**

In their zeal to challenge the entire U.S. pharmaceutical industry, the plaintiffs' indiscriminate attack on Biogen and their attempt to pull Biogen into this litigation amounts to

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<sup>7</sup> Plaintiffs do not even state Avonex®'s WAC at either the time of the alleged purchase or alleged return, merely stating that the WAC was "higher" at the time of return. Although plaintiffs contend that "This case concerns that ... WAC itself is false ..." (Cons. Compl. ¶¶ 7-8), plaintiffs never allege a WAC for Avonex® or any other Biogen drug. Biogen is not even mentioned in Exhibit F to the Consolidated Complaint, which purports to state "Spreads between Published AWP and WACs."

little more than conclusory allegations and theories of guilt by association. The plaintiffs' allegations of fraudulent conduct by Biogen with respect to AWP's are devoid of particulars and fail to meet Rule 9(b) requirements. Allegations of "best prices" violations for Avonex®, the only drug plaintiffs allege they purchased, are based on information and belief and similarly lack sufficient detail. All other allegations in the Consolidated Complaint and Nassau SAC are not specific to Biogen and are devoid of any factual support, direct or indirect, to link Biogen to the alleged wrongful conduct. Thus, they are insufficient under Rule 9(b).

For the foregoing reasons, Biogen respectfully requests that the complaints be dismissed with prejudice, as to it.

Respectfully submitted,

BIOGEN IDEC INC.

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/s/ Kimberly I. Friday

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Dated: March 3, 2006



**Certificate of Service**

I hereby certify that on March 3, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service via LexisNexis File & Serve pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Kimberly I. Friday  
Kimberly I. Friday, Esq.